

EPA Registration Jacket # 74642-10

Vol. 2

CSF

MATERIAL TO BE ADDED TO JACKET

9/18/6/1

REG #

74468-10

Description:

PRN 98-10

check all that apply	
<input type="checkbox"/>	new stamped accepted label
<input checked="" type="checkbox"/>	new CSF
<input type="checkbox"/>	notification

Send to CSC

Instructions:

Attach this sheet to the top of **ALL** material sent to the file room (both loose paper and new material in jackets). This sheet will be imaged; a clear description will aid in finding material in the e-jacket. Remove staples from all material. If returning loose paper then hold together with a binder or paper clip. CSFs should be placed in the CSF folder (if returning jacket) or covered with a red CBI sheet (if returning loose paper). Material to be returned to file room should be place in the appropriate bin.

Reviewer's
Name:

Maria Rodriguez

Date:

Phone:

703-305-6710

Division:

RD



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 74468-10	2. EPA Product Manager J. Miller	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Pre-Amine 4 SC	PM# 23	
5. Name and Address of Applicant (Include ZIP Code) ProActive, LLC P.O. Box 5068 Brookfield, CT 06804 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This is a MINOR FORMULATION AMENDMENT AS PER PR NOTICE 98-10 to submit an alternate CSF to substitute and delete inert ingredients in the formulation and qualifies as a Minor Formulation Amendment for the following reasons: 1. The nominal concentration of the active ingredient does not change; 2. The change does not invalidate any product-specific data submitted in support of the initial registration which will cause additional data to be required; 3. The proposed substitute inert ingredient is approved by the EPA Inerts Branch; 4. The substitute inert ingredient is being used for the same purpose in the formulation. 5. The alternate formulation will not change the acute toxicity category necessitating label changes. This action will not fall within the scope of PRIA and should be completed in 45 days.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Jane M. Miller	Title Agent	Telephone No. (include Area Code) (203) 740-1200	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Agent	
4. Typed Name Jane M. Miller		5. Date March 17, 2009	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MAY 28 2009

Ms. Jane Miller
Biologic Inc
Agent for ProActive, LLC
115 Obtuse Hill
Brookfield, CT 06804

Dear Ms. Miller:

The Agency is in receipt of the following Applications for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10:

Product

CSF

EPA Reg No 74468-10
Pre-Amine 4SC

Alternate, March 9, 2009
- Correspondence of March 9, 2009

Basic, March 16, 2009
- Correspondence of March 17, 2009

Alternate, March 16, 2009
- Correspondence of March 17, 2009

The Registration Division (RD) has conducted a review of these requests for their applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. The Confidential Statements of Formula (CSFs) submitted with the applications are considered "acceptable" and have been placed in our records.

4
March 21/13/10

If you have any questions, please call me directly at 703-305-6249 or María I. Rodríguez of my staff at 703-305-6710.

Sincerely,



Linda Arrington
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs

S046527
12407260

74468-10

BIOLOGIC INC.
agribusiness professionals

On behalf of
"ProActive, LLC"

March 9, 2009

CSF
- ALT

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Room S-4900, 4th Floor
Arlington, VA 22202

Attention: Ms. Joanne Miller (PM #23)

RE: "Pre-Amine 4 SC"; EPA Reg. No. 74468-10
Notification to an Add Alternate Source of Active Ingredient

Dear Ms. Miller:

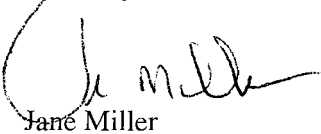
On behalf of ProActive, LLC please find enclosed a notification to submit an alternate CSF which includes an alternate source of the active ingredient for the above mentioned product.

The following documents are enclosed to process this Notification:

1. Application for Pesticide Notification (8570-1)
2. Formulator's Exemption Statement (8570-27)
3. Two (2) copies of the alternative CSF (8570-4)

Should you have any questions, or wish to reach me, please feel free to contact our office at 203-740-1200.

Sincerely,



Jane Miller
Agent to ProActive, LLC



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 74468-10	2. EPA Product Manager J. Miller	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Pre-Amine 4 SC	PM# 23	
5. Name and Address of Applicant (Include ZIP Code) ProActive, LLC P.O. Box 5068 Brookfield, CT 06804 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This is a notification to add an alternate source of active ingredient to the CSF per PR Notice 98-10. This notification is consistent with the provisions of PR Notice 98-10 and the EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Jane M. Miller	Title Agent	Telephone No. (Include Area Code) (203) 740-1200
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent	
4. Typed Name Jane M. Miller	5. Date March 9, 2009	

74468-10



United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address ProActive, LLC P.O. Box 5068 Brookfield, CT 06804	EPA File Symbol/Registration Number 74468-10
	Product Name Pre-Amine 4 SC
	Date of Confidential Statement of Formula (EPA Form 8570-4) March 9, 2009

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Prodiamine

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

(3) Indicate by checking (A) or (B) below which paragraph applies:

- ☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).
- OR
- ☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Prodiamine		
Product ingredient source information may be entitled to confidential treatment		
Signature 	Name and Title Jane M. Miller, Agent	Date 3/9/2009

S 8117212
1-407763

74468-10

BIOLOGIC INC.
agribusiness professionals

On behalf of
"Proactive, LLC"

CSF
-Basic

March 17, 2009

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Room S-4900, 4th Floor
Arlington, VA 22202

Attention: Ms. Joanne Miller (PM #23)

RE: "Pre-Amine 4SC"; EPA Reg. No. 74468-10
Notification to an Add Alternate Source of Active Ingredient

Dear Ms. Miller:

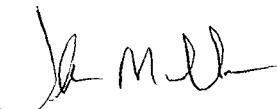
On behalf of ProActive, LLC please find enclosed a notification to add an alternate source of active ingredient to the formulation for the above mentioned product.

The following documents are enclosed to process this Notification:

1. Application for Pesticide Notification (8570-1)
2. One (1) copy of the alternate formulation Confidential Statement of Formula listing the alternate source.

Should you have any questions, or wish to reach me, please feel free to contact our office at 203-740-1200.

Sincerely,



Jane Miller
Agent to ProActive LLC



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 74468-10	2. EPA Product Manager J. Miller	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Pre-Amine 4 SC	PM# 23	
5. Name and Address of Applicant (Include ZIP Code) ProActive LLC P.O. Box 5068 Brookfield, CT 06804 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This is a notification to add an alternate source of active ingredient per PR Notice 98-10. This notification is consistent with the provisions of PR Notice 98-10 and the EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
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Section - IV

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Name Jane M. Miller	Title Agent	Telephone No. (Include Area Code) (203) 740-1200	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Data Application Received (Stamped)
2. Signature 	3. Title Agent		
4. Typed Name Jane M. Miller	5. Date March 17, 2009		

S 84 '379
ID407860

74468-10

BIOLOGIC INC.
agribusiness professionals

March 17, 2009

On behalf of
"ProActive LLC"

MFA
-ALT CSF

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Room S-4900, 4th Floor
Arlington, VA 22202

Attention: Ms. Joanne Miller (PM #23)

RE: "Pre-Amine 4 SC"; EPA Reg. No. 74468-10
MINOR FORMULATION AMENDMENT PER PR NOTICE 98-10

Dear Ms. Miller:

On behalf of ProActive LLC we are submitting this alternate formula for the above mentioned product. This alternate formulation includes a deletion and substitution of inert ingredients in the formulation. As per PR Notice 98-10 this action qualifies as a **Minor Formulation Amendment** for the following reasons:

1. The nominal concentration of the active ingredient does not change;
2. The change does not invalidate any product-specific data submitted in support of the initial registration which will cause additional data to be required;
3. The proposed substitute inert ingredient is approved by the EPA Inerts Branch;
4. The substitute inert ingredient is being used for the same purpose in the formulation.
5. The alternate formulation will not change the acute toxicity category necessitating label changes.

The following documents are enclosed to process this Minor Formulation Amendment:

1. Application for Pesticide Amendment (8570-1)
2. One (1) copy of the currently approved basic formulation CSF (8570-4)
3. Two (2) copies of the proposed alternate formulation CSF (8570-4)
4. One (1) copy of the MSDS for [REDACTED]

We have also enclosed a copy of the recently submitted Application for Pesticide Notification which added an alternate source of active ingredient to the formulation. This information is needed to process this Minor Formulation Amendment.

We look forward to receiving approval of this alternate formulation in 45 days. Should you have any questions, or wish to reach me, please feel free to contact our office at 203-740-1200.

Sincerely,

Jane Miller

Agent to ProActive, LLC

Inert ingredient information may be entitled to confidential treatment

March 17, 2009

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Room S-4900, 4th Floor
Arlington, VA 22202

** Submitted under
74468-10 on
3/17/2009.*

*MOR.
(For comparison)*

Attention: Ms. Joanne Miller (PM #23)

RE: "Pre-Amine 4SC"; EPA Reg. No. 74468-10
Notification to an Add Alternate Source of Active Ingredient

Dear Ms. Miller:

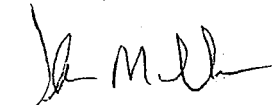
On behalf of ProActive, LLC please find enclosed a notification to add an alternate source of active ingredient to the formulation for the above mentioned product.

The following documents are enclosed to process this Notification:

1. Application for Pesticide Notification (8570-1)
2. One (1) copy of the alternate formulation Confidential Statement of Formula listing the alternate source.

Should you have any questions, or wish to reach me, please feel free to contact our office at 203-740-1200.

Sincerely,



Jane Miller
Agent to ProActive LLC



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 74468-10	2. EPA Product Manager J. Miller	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Pre-Amine 4 SC	PM# 23	
5. Name and Address of Applicant (Include ZIP Code) ProActive LLC P.O. Box 5068 Brookfield, CT 06804 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This is a notification to add an alternate source of active ingredient per PR Notice 98-10. This notification is consistent with the provisions of PR Notice 98-10 and the EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Jane M. Miller		Title Agent	
		Telephone No. (Include Area Code) (203) 740-1200	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Agent	
4. Typed Name Jane M. Miller		5. Date March 17, 2009	

FOR OFFICIAL USE ONLY

FILE SYMBOL	83278-T
REGISTRATION NO.	74466-10

CONFIDENTIAL STATEMENT OF FORMULA ENCLOSED

DATE SUBMITTED	SUBMITTED BY (✓)	
	APPLICANT	BASIC SUPPLIER
JUL - 2 2007		

**Do Not Write Comments,
Formula, or Parts of Formula
on This Envelope**

NOTE

It shall be unlawful—for any person to use for his own advantage or to reveal, other than to the Secretary, or officials or employees of the United States Department of Agriculture or other Federal agencies, or to the courts in response to a subpoena, or to physicians, and in emergencies to pharmacists and other qualified persons, for use in the preparation of antidotes, in accordance with such directions as the Secretary may prescribe, any information relative to formulas of products acquired by authority of Section 4 of the "Federal Insecticide, Fungicide, and Rodenticide Act."

